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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.           | CONFIRMATION NO. |
|--|-------------|----------------------|-------------------------------|------------------|
| 10/048,046   | 01/24/2002  | Thanos Halazonetis   | WST 97AUSA                    | 2775             |
| 270  | 7590        | 02/12/2004           |                               |                  |
| HOWSON AND HOWSON<br>ONE SPRING HOUSE CORPORATION CENTER<br>BOX 457<br>321 NORRISTOWN ROAD<br>SPRING HOUSE, PA 19477 |             |                      | EXAMINER<br>DAVIS, MINH TAM B |                  |
|  |             |                      | ART UNIT<br>1642              | PAPER NUMBER     |
| DATE MAILED: 02/12/2004  |             |                      |                               |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |   |  |
|------------------------------|--------------------------------------|---|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/048,046 | <b>Applicant(s)</b><br>HALAZONETIS ET AL. |  |
|                              | <b>Examiner</b><br>MINH-TAM DAVIS    | <b>Art Unit</b><br>1642                   |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-42 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

**Group 1**, claims 1-6, 21-23, 25, 27, 32, drawn to a nucleic acid of a mitotic checkpoint gene, *chfr*, a fragment thereof, a variant thereof, an antisense fragment or a fragment of SEQ ID NO:1, or a nucleic acid composition that inhibits *chfr* activity.

**Group 2**, claims 7-10, drawn to a polypeptide comprising a Forkhead-associated domain and a Ring Finger domain, SEQ ID NO:2, a fragment thereof, a variant thereof.

**Group 3**, claims 11-13, drawn to a method for determining tumorigenic potential of a cell, comprising detecting the absence of Chfr polynucleotide.

**Group 4**, claims 14-15, drawn to a method for determining tumorigenic potential of a cell, comprising detecting the absence of Chfr polypeptide.

**Group 5**, claims 16-19, drawn to a method for determining tumorigenic potential of a cell, comprising detecting a mutation of Chfr gene.

**Group 6**, claim 20, drawn to a method for determining tumorigenic potential of a cell, comprising detecting the absence of Chfr-mediated ubiquitin-protein ligase activity.

**Group 7**, claim 23, 25, 27-28, 30, 32, 38, drawn to a peptide ligand that binds to CHfr, or an inhibitor of Chfr, wherein said ligand or inhibitor is not an antibody.

**Group 8**, claims 23-24, 25, 27-30, 32, 38, drawn to a peptide ligand that binds to Chfr, or an inhibitor of Chfr, wherein said ligand or inhibitor is an antibody.

**Group 9**, claim 26, drawn to a diagnostic kit, comprising components for a chfr-mediated ubiquitin protein ligase assay.

**Group 10**, claim 31, drawn to a method for identifying a Chfr inhibitor, comprising measuring the mRNA level of Chfr in the presence of a test compound.

**Group 11**, claim 31, drawn to a method for identifying a Chfr inhibitor, comprising measuring the protein level of Chfr in the presence of a test compound.

**Group 12**, Claims 33-37, drawn to a method for identifying a Chfr inhibitor, comprising measuring a Chfr-mediated ubiquitin-protein ligase in the presence of a test compound.

**Group 13**, claims 39-41, drawn to a method for retarding growth of a cancer cell, comprising administering a Chfr inhibitor, which is a polynucleotide.

**Group 14**, claims 39-41, drawn to a method for retarding growth of a cancer cell, comprising administering a Chfr inhibitor, which is an antibody.

**Group 15**, claims 39-41, drawn to a method for retarding growth of a cancer cell, comprising administering a peptide Chfr inhibitor, which is not an antibody.

**Group 16**, claim 42, drawn to a method for assessing the sensitivity of a tumor cell to an agent that disrupts microtubule function, comprising examining the absence of chfr gene.

**Group 17**, claim 42, drawn to a method for assessing the sensitivity of a tumor cell to an agent that disrupts microtubule function, comprising examining the absence of *chfr* protein.

**Group 18**, claim 42, drawn to a method for assessing the sensitivity of a tumor cell to an agent that disrupts microtubule function, comprising examining the absence of *chfr*-mediated ubiquitin-protein ligase activity.

**Group 19**, claim 42, drawn to a method for assessing the sensitivity of a tumor cell to an agent that disrupts microtubule function, comprising examining a mutation of *chfr* gene.

The inventions listed as Groups 1-19 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as groups 1-19 do not relate to a single general inventive concept because they lack the same or corresponding technical feature. The technical feature of group 1 is a nucleic acid of a mitotic checkpoint gene *chfr*, which is shown by Scolnick et al, 1999, Proceed Amer Association Cancer Res, 40: 214, IDS # AR of 06/03/02. The claimed invention thus lacks novelty, and does not make a contribution over the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, YVONNE EYLER can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MINH TAM DAVIS

PATENT EXAMINER

February 06, 20204